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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/812,292

03/29/2004

Dennis E. Discher

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12/09/2008

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/812,292	<b>Applicant(s)</b> DISCHER ET AL.	
	<b>Examiner</b> ERIC E. SILVERMAN	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/10/2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/2008 has been entered.

Pursuant to amendment, claims 1-16 are pending.

### ***Priority***

Applicants' comments about priority have been fully considered, and are persuasive. The instant claims, insofar as they read on the elected species, are granted benefit of the filing date of Application No. 09/460,605, Now U.S. Patent No. 6,835,394. The 2002 Discher reference is not a competent reference against this ApplicationNote that because the elected species is not currently allowable.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is based on an amendment that enters new matter into the claims.

Claim 1 now recites “without secondary chemical processing”. The originally filed disclosure does not disclose secondary chemical processing, either as a positive or negative recitation. Nor have Applicants' pointed to any portion of the disclosure that supports this newly added limitation.

The remaining claims are rejected as ultimately depending on claim 1 and thus incorporating the new matter thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “secondary chemical processing”. It is not clear what types of chemical processing are “secondary,” and thus disallowed in the claimed method, as opposed to those that are “primary” or “tertiary,” and thus allowed in the claimed method. The specification offers insufficient guidance. The artisan would not know what types of chemical processing are forbidden, and would thus be unable to determine the metes and bounds of the claimed invention.

Claim 1 recites “determining the appropriate blend ratio (mol %) of hydrolysable PEO-block copolymer of at least one hydrophilic component and at least one more

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hydrophobic PEO-block copolymer component." It is unclear how many copolymers are present, and which component belongs to which copolymer. Does the claim intend that the "at least one hydrophilic component and at least one more hydrophobic PEO-block copolymer component" be part of the same copolymer, or different copolymers? Does the "at least one hydrophilic component" refer to PEO, or does it refer to some additional hydrophilic component? Is the "hydrophobic PEO-block copolymer component" part of the "PEO block copolymer of at least one hydrophilic component", or are the former and the latter separate copolymers? It is not clear if this step refers to determining an appropriate ratio of components in a single copolymer, or to determining an appropriate ratio of two different copolymers. If the former, it is not clear whether the copolymer must have at least two components (PEO, which is a hydrophilic component, and a hydrophobic component), or if the copolymer must have three components (PEO, a hydrophilic component that is not PEO, and a hydrophobic component).

Claim 1 also refers to a "hydrophobic block copolymer to effect controlled polyester chain hydrolysis in the membrane." This element must be such that "when combined with hydrophilic PEO [specified factors] control encapsulant release kinetics. It is not clear if "hydrophilic PEO" refers to one (or more) of the previously mentioned "hydrolysable PEO-block copolymer[s]", or if it refers to a hypothetical situation where the "hydrophobic block copolymer" is combined with pure PEO (PEO being a hydrophilic material).

The remaining claims are rejected at least for depending on claim 1 without clarifying the issues discussed above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piskin et al. J Biomater. Sci. Polymer Edn., 1995, in view of Won et al., Science, 1999, both are of record.

The elected species is a method of making a mixed-micelle composition by adding to water a PEG-PLA block copolymer and a PEG-PBD (PBD is polybutadiene) block copolymer, wherein doxorubicin is encapsulated in the micelle. Various claims recite properties of the component copolymers and encapsulant; Applicants' submission that these claims read on the elected species is an admission that the elected species has the claimed properties.

Piskin teaches a method of using copolymer made from PEG-PLA (referred to as PEG/PDLLA in the article) to form micelles. The polymers are used to encapsulate doxorubicin. The release of the drug is controlled by degradation of the PLA component of the micelles.

What is lacking is blending the PEG-PLA with PEG-PBD to form the micelles.

Won teaches that PEG-PBD can be used to form micelles.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to form a micelle from a mixture of PEG-PBD and PEG-PLA.

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MPEP 2144.05 states as follows:

“It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be

used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie* obvious). \*\*

Here, the art teaches that PEG-PLA and PEG-PBD are both known to make micelles. It therefore follows that a method of forming micelles by mixing two components known to form micelles constitutes *prima facie* obvious subject matter. Further, the record does not indicate any unexpected result stemming from the combination. For example, the specification at paragraph [0026] (referring to the published application) notes that delivery of the active agent from the micelles is controlled by degradation of the hydrolysable component (PLA in the elected species). Pisken also teaches that the degradation of PLA controls drug release in PEO-PLA micelles. Accordingly, the record does not indicate that the resulting combination has any unexpected properties.

***Conclusion***

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/  
Examiner, Art Unit 1618